INTERNATIONAL TRADE COMMISSION

[Investigation No. 337-TA-1145]

Certain Botulinum Toxin Products, Processes for Manufacturing or Relating to Same and Certain Products Containing Same Commission Final Determination Finding a Violation of Section 337; Issuance of a Limited Exclusion Order and a Cease and Desist Order; Termination of the Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has found a violation of section 337 in the above-captioned investigation. The Commission has determined to issue a limited exclusion order ("LEO") prohibiting the importation by respondents Daewoong Pharmaceuticals Co., Ltd. ("Daewoong") of Seoul, South Korea and Evolus, Inc. ("Evolus") of Irvine, California (collectively, "Respondents") of certain botulinum toxin products, processes for manufacturing or relating to same and certain products containing same. The Commission has also issued a cease and desist order ("CDO") directed to respondent Evolus. The investigation is terminated.

FOR FURTHER INFORMATION CONTACT: Houda Morad, Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 708-4716. Copies of non-confidential documents filed in connection with this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov*. For help accessing EDIS, please email EDIS3Help@usitc.gov. General information concerning the Commission may also be obtained by accessing its Internet server at *https://www.usitc.gov*. The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov*. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205-1810.

SUPPLEMENTARY INFORMATION: On March 6, 2019, the Commission instituted this investigation under section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337 ("section 337"), based on a complaint filed by Medytox Inc. of Seoul, South Korea; Allergan Limited of Dublin, Ireland; and Allergan, Inc. of Irvine, California (collectively, "Complainants"). *See* 84 FR 8112-13 (Mar. 6, 2019). The complaint, as supplemented, alleges a violation of section 337 based upon the importation and sale in the United States of certain botulinum toxin products, processes for manufacturing or relating to same and certain products containing same by reason of misappropriation of trade secrets, the threat or effect of which is to destroy or substantially injure a domestic industry in the United States. *See id.* The notice of investigation names Daewoong and Evolus as respondents in this investigation. *See id.* The Office of Unfair Import Investigations is also a party to the investigation. *See id.*

On July 6, 2020, the Administrative Law Judge ("ALJ") issued a final initial determination ("FID") finding a violation of section 337 based on the importation and sale in the United States of Respondents' botulinum neurotoxin products by reason of the misappropriation of trade secrets, the threat or effect of which is to destroy or substantially injure an industry in the United States. *See* FID at 273. The ALJ issued a recommended determination ("RD") recommending that, if a violation is found, the Commission issue: (1) an LEO barring entry of certain botulinum toxin products that are imported and/or sold by respondents Daewoong and Evolus; and (2) a CDO against Evolus. The RD also recommends that the Commission impose a bond based on price differential during the period of Presidential review.

On July 28, 2020, the Commission issued a notice requesting statements on the public interest. *See* 85 FR 46711 (Aug. 3, 2020) ("the PI Notice"). On August 17-18, 2020, several non-parties filed submissions in response to the PI Notice.

On September 21, 2020, the Commission issued a notice determining to review the FID in part. *See* 85 FR 60489-90 (Sept. 25, 2020) ("the WTR/Remedy Notice"). Specifically, the Commission determined to review the FID's findings with respect to subject matter jurisdiction, standing, trade secret existence and misappropriation, and domestic industry, including the existence of such domestic industry as well as any actual or threatened injury thereto. *See id.* The Commission determined not to review the remainder of the FID. *See id.* The Commission's notice also requested written submissions on remedy, the public interest, and bonding. *See id.*

On October 9, 2020, the parties, including the IA, filed written submissions in response to the WTR/Remedy Notice, and on October 16, 2020, the parties filed responses to each other's submissions. In addition, on October 5-9, 2020, several non-parties filed submissions on the proposed remedy and/or the public interest in response to the WTR/Remedy Notice.

Having examined the record of this investigation, including the FID, the RD, and the parties' and non-parties' submissions, the Commission has determined to affirm the FID in part and reverse in part. Specifically, as explained in the Commission Opinion filed concurrently herewith, the Commission has determined to affirm with modification the FID's findings with respect to subject matter jurisdiction, standing, domestic industry as to BOTOX®, and trade secret existence and misappropriation as it relates to Medytox's manufacturing processes. The Commission has also determined to reverse the FID's finding that a trade secret exists with respect to Medytox's bacterial strain. All findings in the FID that are not inconsistent with the Commission's determination are affirmed.

Accordingly, the Commission finds that there is a violation of section 337. The Commission has determined that the appropriate remedy is an LEO against Respondents' botulinum toxin products, and a CDO against Evolus, barring Respondents' unfair acts for a

duration of 21 months. The Commission has also determined that the public interest factors enumerated in subsections 337(d)(1) and (f)(1) (19 U.S.C. 1337(d)(1), (f)(1)) do not preclude the issuance of the LEO and CDO. The Commission has further determined to set a bond during the period of Presidential review in an amount of $441 per 100U vial of Respondents' accused products.

The Commission's orders and opinion were delivered to the President and to the United States Trade Representative on the day of their issuance.

The investigation is terminated.

The Commission's vote on this determination took place on December 16, 2020.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Issued: December 16, 2020.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2020-28158 Filed: 12/21/2020 8:45 am; Publication Date: 12/22/2020]